

(ii) The pregnant woman's informed consent be obtained by an individual other than the individual who obtained the informed consent for the pregnant woman's abortion;

(iii) The pregnant woman be at or over the age of majority in the jurisdiction in which the pregnant woman's donation is made; and

(iv) The Informed Consent Form include a statement that the decision to have an abortion and the method of abortion have not been affected by the decision whether to donate human fetal tissue.

■ 4. Amend § 46.206 by adding paragraphs (c) through (i) to read as follows:

§ 46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

* * * * *

(c) At all stages in the process to acquire or otherwise obtain human fetal tissue for use in research, there shall be no enticements, benefits, or financial incentives provided to the pregnant woman or attending physician to incentivize the occurrence of an abortion or the donation or acquisition of human fetal tissue.

(d) No person who solicits or knowingly acquires, receives, or accepts a donation of human fetal tissue for use in research shall provide valuable consideration for the costs associated with the abortion that is the source of the human fetal tissue used or to be used in the research.

(e) No person who solicits or knowingly acquires, receives, or accepts a donation of human fetal tissue for use in research shall provide valuable consideration for the costs associated with the donation or acquisition of human fetal tissue.

(f) For purposes of paragraphs (d) and (e) of this section, the term "valuable consideration" includes all payments other than reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.

(g) Human fetal tissue obtained by donation from a woman occurring after [the effective date of the final rule] may be used in research only if an informed consent that meets the applicable requirements of § 46.204(k) has been obtained with respect to the tissue.

(h) Research involving human fetal tissue can use human fetal tissue from elective abortions only if such tissue is acquired or otherwise obtained from a Federal or State Government, a Federal or State Government-owned entity, university, college, accredited degree-

granting institution of higher education, university hospital, or academic medical center.

(i) Once human fetal tissue is no longer to be used in research, it shall be treated respectfully and disposed of reasonably and in compliance with any additional laws or regulations imposed by applicable state law.

PART 75—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR HHS AWARDS

■ 5. The authority citation for 45 CFR part 75 continues to read as follows:

Authority: 5 U.S.C. 301.

■ 6. Amend § 75.364 by adding paragraph (a)(1), adding and reserving paragraph (a)(2) and adding paragraph (d) to read as follows:

§ 75.364 Access to records.

(a) * * *

(1) For non-Federal entities that engage in human fetal tissue research pursuant to a Federal award, the HHS awarding entity, Inspectors General, the Comptroller General of the United States, and the pass-through entity, or any of their authorized representatives, must have the right of access to:

(i) Copies of the informed consent forms signed by each pregnant woman who is the source of human fetal tissue used by the non-Federal entity in research, which may be redacted with respect to the name and signature of the woman;

(ii) all documents, papers, or other records as are necessary to establish that the human fetal tissue was not obtained or transferred for valuable consideration, as that term is defined in 45 CFR 46.206(f);

(iii) all documents, papers, or other records as are necessary to establish that federal funds were not used to acquire or otherwise obtain the human fetal tissue from elective abortions; and

(iv) personnel familiar with such documents, for purposes of interview and discussion concerning such documents, at reasonable times and locations.

(2) [Reserved]

* * * * *

(d) For purposes of this section, "human fetal tissue" shall have the definition ascribed to the term in 42 U.S.C. 289g-1(g).

■ 7. Add § 75.478 to subpart E to read as follows:

§ 75.478 Expenses associated with acquiring human fetal tissue for research.

Expenses associated with the acquisition of human fetal tissue from

elective abortions for use in research are not allowable expenses under Federal awards from an HHS awarding agency.

Dated: December 29, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020-29107 Filed 1-11-21; 4:15 pm]

BILLING CODE 4151-26-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 5b

[Docket Number NIH-2016-0002]

RIN 0925-AA62

Privacy Act; Implementation

AGENCY: Department of Health and Human Services.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or Department) proposes to exempt confidential source identifying information in a system of records maintained by the National Institutes of Health (NIH) from certain requirements of the Privacy Act. The affected system of records is 09-25-0165, "National Institutes of Health (NIH) Office of Loan Repayment and Scholarship (OLRS) Record System, HHS/NIH/OD" (to be renamed "NIH Loan Repayment Records"). Elsewhere in today's **Federal Register**, HHS/NIH has published an updated system of records notice (SORN) for system 09-25-0165 for public notice and comment.

DATES: Submit either electronic or written comments regarding this document by March 15, 2021.

ADDRESSES: You may submit comments, identified by Docket Number NIH-2015-0002, via any of the following methods:

Electronic Submission

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions provided for submitting comments.

Written Submission

Submit written submissions in the following ways:

- **Fax:** 301-402-0169.
- **Mail:** Daniel Hernandez, Acting NIH Regulations Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, MD 20852.

In order to ensure more timely processing of comments, HHS/NIH is no

longer accepting notice of proposed rulemaking (NPRM) comments submitted to the agency by email. HHS/NIH encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No. for this rulemaking. All comments received may be posted without change to <https://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to

<https://www.regulations.gov> and follow the instructions provided for conducting a search, using the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

General questions about the proposed exemptions may be submitted to Daniel Hernandez, Acting NIH Regulations Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, MD 20852, telephone 301-435-3343, fax 301-402-0169, email dhernandez@od.nih.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the NIH Loan Repayment Programs and System of Records 09–25–0165

The NIH Loan Repayment Programs (LRPs) are administered by the Division of Loan Repayment within NIH's Office of Extramural Research (HHS/NIH/OER/DLR, hereafter referred to as DLR). DLR provides repayment of student loans for approved applicants to encourage outstanding health professionals to pursue careers in biomedical, behavioral, social, and clinical research. Research health professionals who owe qualified educational debt and who meet eligibility criteria may apply for student loan repayment. Loan repayments utilize a peer review process to determine which applicants to approve. The peer review process is committee-based, with a peer review group comprised of individual reviewers, referees, or other recommenders (hereafter collectively referred to as reviewers). Reviewers are primarily non-government experts qualified by training and experience in scientific or technical fields, or as authorities knowledgeable in disciplines and fields related to the areas under review. Reviewers give DLR expert recommendations and materials (such

as ratings, summaries, and communications) about applicants' suitability, eligibility, or qualifications for student loan repayments under express promises that the reviewers will not be identified as the sources of the information. DLR uses the information solely for the purpose of determining applicants' suitability, eligibility, or qualifications for federal loan repayment. System of records 09–25–0165 covers records about health professionals who apply for student loan repayments and about other categories of individuals who are related to the applications. Records about those record subjects include materials and recommendations provided to DLR by reviewers which identify, or could enable identification of, those confidential sources.

II. Proposed Exemptions and Affected Records

HHS/NIH is proposing to exempt materials about LRP applicants in system of records 09–25–0165 from certain provisions of the Privacy Act (5 U.S.C. 552a). The exemption applies only to the extent that a disclosure would reveal the identity of the reviewer or referee who furnished information to the Government under an express promise that his or her identity would be held in confidence. We propose to exempt the system of records from (c)(3), pertaining to the accounting of disclosures, and (d)(1) through (d)(4), pertaining to access, amendment, and notification provisions, based on subsection (k)(5) of the Act (5 U.S.C. 552a(k)(5)). Because records in system of records 09–25–0165 contain information not only about applicants, but also about the reviewers, the proposed exemptions are necessary to enable NIH to prevent applicants from having access to information about the identity of individuals who provided NIH with an expert review or referee report under an express promise of confidentiality. Notwithstanding the exemptions, NIH will consider any requests for notification, access, and amendment that are addressed to the System Manager, as provided in the SORN for system of records 09–25–0165, and to any request for an accounting of disclosures.

Under the Privacy Act of 1974, as amended (5 U.S.C. 552a), individuals have access and amendment rights with respect to records about them in a federal agency system of records, and the right to seek an accounting of certain disclosures made of the records about them, but the Act permits certain types of systems of records (identified in subsections (j) and (k) of the Act) to be

exempted from those requirements of the Act. Subsection (k)(5) permits the head of an agency to promulgate rules to exempt from the requirements in 5 U.S.C. 552a(c)(3) and (d)(1) through (4) investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for access to federal civilian employment, military service, federal contracts, or access to classified information, to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the government under an express promise that the identity of the source would be held in confidence. Referee reports and reviews in system of records 09–25–0165 qualify for exemption under 5 U.S.C. 552a(k)(5), when provided to DLR under an express promise of confidentiality, because it is investigatory material that DLR compiles solely for the purpose of determining applicants' suitability, eligibility, or qualifications for federal loan repayment awards, which are implemented by contracts.

III. Exemption Rationales

The proposed exemptions are necessary to maintain the integrity of the DLR peer review and award processes, which depend on receiving accurate, objective, and unbiased recommendations and evaluations from reviewers about loan repayment applications. Protecting reviewer identities as the sources of the information they provide protects them from harassment, intimidation, and other attempts to improperly influence award outcomes, and ensures that they are not reluctant to provide sensitive information or frank assessments. Case law has held that exemptions promulgated under subsection (k)(5) may protect source-identifying material even where the identity of the source is known to the subject individual(s).

The specific rationales that support the exemptions, as to each affected Privacy Act provision, are as follows:

- **Subsection (c)(3).** An exemption from the requirement to provide an accounting of disclosures to record subjects is needed to protect the identity of any reviewer source who is expressly promised confidentiality. Providing an accounting of disclosures to an individual who is related to the application under assessment or evaluation could identify particular reviewers as sources of recommendations or evaluative input received, or to be received, on the application. Inappropriately revealing their identities in association with the nature and scope of their assessments or

evaluations could lead them to alter or destroy their assessments or evaluations or subject them to harassment, intimidation, or other improper influence, which would impede or compromise the fairness and objectivity of the loan repayment application review process.

- *Subsection (d)(1)*. An exemption from the access requirement is needed both during and after an award application review proceeding to avoid inappropriately revealing the identity of any source who was expressly promised confidentiality. Protecting these records from access by record subjects is necessary for the integrity of the review process. It ensures such sources provide candid assessments or evaluations to the government without fear that their identities as linked to a specific work product will be revealed inappropriately. Allowing an individual applicant who is the subject of an assessment or evaluation, or another record subject who has a relationship to the application, to access material that would reveal a reviewer could interfere with or compromise the objectivity and fairness of award application review proceedings, constitute an unwarranted invasion of the personal privacy of the reviewer, and violate the express promise of confidentiality made to the reviewer.

- *Subsection (d)(2) through (4)*. An exemption from the amendment provisions is necessary while one or more related application review proceedings are pending, but only if and to the extent that disclosure of information in the amendment request process would reveal inappropriately the identity of any reviewer source who was expressly promised confidentiality. An exemption will be limited to allowing the agency, when processing an amendment request by an applicant or other subject individual, to avoid disclosing the existence of the record sought to be amended and its contents, if doing so would reveal the identity of any reviewer who was expressly promised confidentiality. Revealing the identity of a reviewer to an individual applicant or other subject individual would interfere with the agency's application review process and constitute an unwarranted invasion of the personal privacy of the reviewer and would violate the express promise of confidentiality made to the reviewer.

Accordingly, pursuant to 5 U.S.C. 552a(k)(5), NIH proposes to exempt records about particular LRP applicants in system of records 09–25–0165 NIH Division of Loan Repayment Record System from the access, amendment, and accounting of disclosures

provisions of the Privacy Act (5 U.S.C. 552a(c)(3) and (d)(1) through (4)), to the extent, and based on the specific rationales stated above.

Notwithstanding the exemptions, NIH will consider any request for access or amendment that is addressed to the System Manager as provided in the SORN for system of records 09–25–0165, and to any request for an accounting of disclosures.

Analysis of Impacts

I. Review Under Executive Orders 12866, 13563, and 13771

The agency has reviewed this proposed rule under Executive Orders 12866 and 13563, which direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to maximize the net benefits. The agency believes that this proposed rule is not a significant regulatory action under Executive Order 12866, and therefore does not constitute an E.O. 13771 regulatory action, because it will not (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866. legal mandates, the President's priorities, or the principles set forth in Executive Order 12866. This rule removes certain Privacy Act rights from the subjects of these records in accordance with criteria established in subsection (k)(5) of the Privacy Act (5 U.S.C. 552a(k)(5)). This decision is based on a showing that agency compliance with all of the Privacy Act requirements with respect to those records would harm the effectiveness or integrity of the agency function or process for which the records are maintained (in this case, NIH research and development loan award processes).

II. Review Under the Regulatory Flexibility Act (5 U.S.C. 601–612)

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant regulatory impacts of a rule on small entities. Because the proposed

rule imposes no duties or obligations on small entities, we have determined, and the Director certifies, that the proposed rule will not have a significant economic impact on a substantial number of small entities.

III. Review Under the Unfunded Mandates Reform Act of 1995 (Section 202, Pub. L. 104–4)

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$144 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. The agency does not expect that this proposed rule would result in any 1-year expenditure by state, local, and tribal governments that would meet or exceed this amount.

IV. Review Under the Paperwork Reduction Act of 1995 (44 U.S.C. 35–1 *et seq.*)

This proposed rule does not contain any information collection requirements subject to the Paperwork Reduction Act.

V. Review Under Executive Order 13132, Federalism

This proposed rule will not have any direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, the requirements of Executive Order 13132 are inapplicable.

List of Subjects in 45 CFR Part 5b

Privacy.

For the reasons set out in the preamble, the Department amends part 5b of title 45 of the Code of Federal Regulations, as follows:

PART 5b—PRIVACY ACT REGULATIONS

■ 1. The authority citation for Part 5b continues to read as follows:

Authority: 5 U.S.C. 301, 5 U.S.C. 552a.

■ 2. Amend § 5b.11 by adding paragraph (b)(2)(iv)(D) as follows:

§ 5b.11 Exempt systems.

* * * * *

(b) * * *

(2) * * *

(iv)

(D) NIH Division of Loan Repayment Record System, 09–25–0165.

Dated: November 20, 2020.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

Approved: December 22, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–28884 Filed 1–12–21; 8:45 am]

BILLING CODE 4140–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[WC Docket No. 12–375; DA 20–1446; FRS 17293]

Petition for Reconsideration of Action in Proceeding

Correction

In proposed rule document 2020–27982 appearing on page 83000 in the issue of Monday, December 21, 2020, make the following correction:

(1) On page 83000, in the second column, in the **DATES** section, change “January 20, 2021” to read “January 21, 2021.”

[FR Doc. C1–2020–27982 Filed 1–12–21; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 218

[Docket No. 201207–0329]

RIN 0648–BJ90

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to U.S. Navy Construction at Naval Station Norfolk in Norfolk, Virginia

Correction

In proposed rule document 2020–27300 appearing on pages 83001 through 83026 in the issue of Monday, December 21, 2020, make the following correction:

(1) On page 83001, in the second column, in the **DATES** section, change “January 20, 2021” to read “January 21, 2021.”

[FR Doc. C1–2020–27300 Filed 1–12–21; 8:45 am]

BILLING CODE 1301–00–D